TENT COOPERATION TRE. /

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING SUBMISSION OR TRANSMITTAL OF PRIORITY DOCUMENT

(PCT Administrative Instructions, Section 411)

To:

FLOAM, D., Andrew
Needle & Rosenberg, P.C.
Suite 1200
The Candler Building
127 Peachtree Street, N.E.
Atlanta, GA 30303-1811
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year) 09 July 2001 (09.07.01)	
Applicant's or agent's file reference 19141.0039P1	**IMPORTANT NOTIFICATION**
International application No. PCT/US00/16507	International filing date (day/month/year) 15 June 2000 (15.06.00)
International publication date (day/month/year) 28 December 2000 (28.12.00)	Priority date (day/month/year) 18 June 1999 (18.06.99)
Applicant SPECTRX, INC. et al	

1. The applicant is hereby notified of the date of receipt (except where the letters "NR" appear in the right-hand column) by the International Bureau of the priority document(s) relating to the earlier application(s) indicated below. Unless otherwise indicated by an asterisk appearing next to a date of receipt, or by the letters "NR", in the right-hand column, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).

2. This updates and replaces any previously issued notification concerning submission or transmittal of priority documents.

3. An **asterisk(*)** appearing next to a date of receipt, in the right-hand column, denotes a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b). In such a case, **the attention of the applicant is directed** to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

4. The **letters "NR"** appearing in the right-hand column denote a priority document which was not received by the International Bureau or which the applicant did not request the receiving Office to prepare and transmit to the International Bureau, as provided by Rule 17.1(a) or (b), respectively. In such a case, **the attention of the applicant is directed** to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

Priority date	Priority application No.	Country or regional Office or PCT receiving Office	Date of receipt of priority document
18 June 1999 (18.06.99)	60/139,943	US	23 Nove 2000 (23.11.00)
20 July 1999 (20.07.99)	09/357,471	US	01 Augu 2000 (01.08.00)
20 July 1999 (20.07.99)	09/357,452	US	08 Dece 2000 (08.12.00)

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer

Catherine Massetti

Telephone No. (41-22) 338.83.38

PA NT COOPERATION TREAT

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 08 February 2001 (08.02.01)	
International application No. PCT/US00/16507	**Applicant's or agent's file reference** 19141.0039P1
International filing date (day/month/year) 15 June 2000 (15.06.00)	**Priority date** (day/month/year) 18 June 1999 (18.06.99)
Applicant HATCH, Michael, R.	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

05 January 2001 (05.01.01)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer Claudio Borton
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREA

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION

(PCT Rule 44.1)

To:
NEEDLE & ROSENBERG, P.C.
Suite 1200
The Candler Building
127 Peachtree Street, N.E.
Atlanta, GA 30303-1811
UNITED STATES OF AMERICA

Applicant's or agent's file reference 19141.0039P1	Date of mailing *(day/month/year)* 04/09/2000
International application No. PCT/US 00/16507	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
Applicant SPECTRX, INC. et al.	International filing date *(day/month/year)* 15/06/2000

1. [X] The applicant is hereby notified that the International Search Report has been established and is transmitted herewith.

Filing of amendments and statement under Article 19:
The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet. DAF/mmD

Where? Directly to the International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Fascimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. [ ] The applicant is hereby notified that no International Search Report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. [ ] **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

[ ] the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

[ ] no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

Within **19 months** from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within **20 months** from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the International Searching Authority European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Audrey Rummery

Form PCT/ISA/220 (July 1998)

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped),whether

(i) the claim is unchanged;

(ii) the claim is cancelled;

(iii) the claim is new;

(iv) the claim replaces one or more claims as filed;

(v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where onginally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."

2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."

3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."

4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international appplication is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the International Bureau, also file a copy of such amendments with the International Preliminary Examining Authority (see Rule 62.2(a), first sentence).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, where upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.

BNSDOCID: <XSISA220NOENP4_I_>

PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

THOMSON, P.A.
POTTS, KERR & CO
15 Hamilton Square
BIRKENHEAD, MERSEYSIDE CH41 6BR
GRANDE BRETAGNE

PCT

WRITTEN OPINION

(PCT Rule 66)

Date of mailing *(day/month/year)*	20.03.2001
Applicant's or agent's file reference: EB 5783	**REPLY DUE** **within 3 month(s)** from the above date of mailing

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US00/16507	15/06/2000	18/06/1999

International Patent Classification (IPC) or both national classification and IPC

A61B5/00

Applicant

SPECTRX, INC. et al.

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

I	☒	Basis of the opinion
II	☐	Priority
III	☒	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☐	Lack of unity of invention
V	☒	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☐	Certain document cited
VII	☒	Certain defects in the international application
VIII	☒	Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 18/10/2001.

Name and mailing address of the international preliminary examining authority:

European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized officer / Examiner

Fontenay, P

Formalities officer (incl. extension of time limits)

Edel, M

Telephone No. +49 89 2399 2426

I. Basis of the opinion

1. This opinion has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".)*:

Description, pages:

1-8 as originally filed

Claims, No.:

1-17 as originally filed

Drawings, sheets:

1/4-4/4 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application,

☒ claims Nos. 3, 5, 8, 9, 13-17 ,

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 3, 5, 8, 9, 13-17 are so unclear that no meaningful opinion could be formed (*specify*):
see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos. .

2. A written opinion cannot be drawn due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrialapplicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1, 2, 4, 6, 7, 10
Inventive step (IS)	Claims	11, 12

Industrial applicability (IA) Claims

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Re Item III

III.1 The subject-matter of claims 3, 5, 8, 9, 15 and 16 differs from the method respectively system known from the prior art (see comments under section V) by the content of the information which is provided to the user. The content of information is not as such technical nature so that said claims 3, 5, 8 and 9 do not provide any technical contribution to the prior art.

III.2 The subject-matter of claims 14 and 17 is not clearly defined contrary to the requirements of Article 6 PCT.

Although claims 14 and 17 relate to a system, they include features which are directly related to a method. In particular, the feature of a processor being operative to store data ... during periods of physical exercise, compare glucose levels during the physical exercise" relate to the use of the claimed system It is in particular not clear which additional limitation results from the proposed wording over the system defined in claim 6.

The same objection applies to claim 17 which also refers to physical exercise.

III.3 The subject-matter of claim 13 is not clearly defined (Article 6 PCT).

The features of claim 13 are not sufficient in order to allow the skilled man to determine said threshold level. The mere reference to physical exercise and to a physiologically dependent goal without indicating how the threshold is determined is too vague.

Re Item V Reasoned statement under Rule 66.2 with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: US-A-4731726
D2: US-A-4686624

V.1 The subject-matter of claim 1 is not new in the sense of Article 33(2) PCT considering the teaching of document D1.

Document D1 discloses a method for assisting an individual in weight management comprising the steps of setting a maximum desired glucose level for an individual (see D1, column 2, lines 28-47) and of recording glucose levels at multiple times during a day for the individual to obtain levels after at least one meal and comparing post meal glucose levels with the maximum desired glucose level (see D1, column 17; lines 10-14).

All the features of claim 1 are known in combination from D1. The method defined in claim 1 is accordingly not new.

V.2 It follows from the passage in column 17, lines 10-14 that a indicator is generated when it is determined that a post meal glucose level exceeds the maximum glucose level (claim 2). In D1, the defined method also comprises the step of receiving input from the individual indicating the occurrence of a meal event (claim 4 - see D1, column 14, line 60 - column 15, line 25).

The subject-matter of claims 2 and 4 is therefore also not new.

V.3 The objection raised above as to the method of claim 1 apply mutatis mutandis to the system defined in independent claim 6 and dependent claim 7 which accordingly also refer to subject-matter anticipated by the prior art.

V.4 The method of claim 10 is also anticipated by document D1.

It si in particular noted that the system disclosed in D1 may be use at any time of the day and that the system is adapted for recording exercise (see D1, column 9, lines 12-43). It follows that the method for assisting an individual in exercise is implicitly disclosed in D1 (see also column 17, lines 10-14).

V.5 The subject-matter of dependent claims 11 and 12 is not inventive in the sense of Article 33(3) PCT.

In D1, the glucose concentration is regulated by a quantity of insulin. However, It is common knowledge that the first parameter which influences glucose concentration in blood is dietary intake. In fact this common knowledge could be confirmed by any medical doctor. It is also common knowledge that exercise shall increase the "burning" of glucose so that the additional features of dependent claims 11 and 12 would be obvious and merely refer to normal practise for the skilled man.

Re Item VII Certain defects in the international application

VII.1 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 and D2 is not mentioned in the description, nor are these documents identified therein.

VII.2 Independent claim should be drafted in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate.

VII.3 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

VII.4 The application documents should be self-contained. The applicant should refer to the Guidelines PCT/GL/3, Chapter II, § 4.17. In present case, the wording "incorporated by reference" as it appears on page 3, lines 2 and 3 should be deleted.

Re Item VIII Certain observations on the international application

VIII.1 The various definitions of the invention given in independent claims 1 and 10 as to a method and claims 6 and 14 as to a system are such that the claims as a whole are not concise, contrary to Article 6 PCT. Moreover, lack of clarity of the claims as a whole arises, since the plurality of independent claims makes it difficult, if not impossible, to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of the

protection. The claims should include the minimum necessary number of independent claims in any one category, Rule 6.1(a) PCT, with dependent claims as appropriate, Rule 6.4 PCT

Comments:

The applicant may file possible amendments by way of replacement pages in the manner stipulated by Rule 66.8(a) PCT. In particular, fair copies of the amendments should be filed preferably in triplicate.

Moreover, the applicant's attention is drawn to the fact that, as a consequence of Rule 66.8(a) PCT the examiner is not permitted to carry out any amendments under the PCT procedure, however minor these may be.

In order to facilitate the examination of the conformity of the amended application with the requirements of Article 34(2)(b) PCT, the applicant is requested to clearly identify the amendments carried out, no matter whether they concern amendments by addition, replacement or deletion, and to indicate the passages of the application as filed on which these amendments are based (see also Rule 66.8(a) PCT).

PATENT COOPERATION TREAT

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION** see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
19141.0039P1		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US 00/ 16507	15/06/2000	18/06/1999
Applicant		
SPECTRX, INC. et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language,** the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   [ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   [ ] contained in the international application in written form.

   [ ] filed together with the international application in computer readable form.

   [ ] furnished subsequently to this Authority in written form.

   [ ] furnished subsequently to this Authority in computer readble form.

   [ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   [ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [ ] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 1

   [ ] as suggested by the applicant.

   [X] because the applicant failed to suggest a figure.

   [ ] because this figure better characterizes the invention.

   [ ] None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/16507

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B G06F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 731 726 A (ALLEN III LYLE M) 15 March 1988 (1988-03-15)	1,6,10, 14
A	column 2, line 28 - line 46 column 3, line 64 -column 4, line 32 column 9, line 12 -column 10, line 48 column 13, line 33 -column 16, line 34; tables 1-5	2-5,7-9, 11-13, 15-17

X	US 4 686 624 A (D.BLUM ET AL) 11 August 1987 (1987-08-11)	1-9
A	column 3, line 43 -column 6, line 56; tables 1-4	10-17

	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 August 2000	04/09/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Weihs, J

Form PCT/ISA/210 (second sheet) (July 1992)

International Application No
PCT/US 00/16507

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 290 683 A (DIVA MEDICAL SYSTEMS BV) 17 November 1988 (1988-11-17)	10-17
A	page 2, line 40 -page 3, line 16 page 5, line 11 -page 6, line 13; table 1	1-9
X	EP 0 462 466 A (MILES INC) 27 December 1991 (1991-12-27)	10-17
A	column 1, line 56 -column 2, line 14 column 2, line 35 -column 7, line 23; tables 1-9	1-9
A	WO 97 28737 A (NOKIA MOBILE PHONES LTD ;OKKONEN HARRI (FI); HEINONEN PEKKA (FI)) 14 August 1997 (1997-08-14) page 6, line 15 -page 9, line 26; table 1	1,6,10, 14

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 4731726	A	15-03-1988	CA	1304135 A	23-06-1992
US 4686624	A	11-08-1987	FR	2544525 A	19-10-1984
			AT	39582 T	15-01-1989
			CA	1210867 A	02-09-1986
			DE	3475840 D	02-02-1989
			EP	0128054 A	12-12-1984
			JP	60051970 A	23-03-1985
EP 0290683	A	17-11-1988	CA	1330581 A	05-07-1994
			DK	229288 A	16-02-1989
			JP	1025837 A	27-01-1989
			US	5019974 A	28-05-1991
			US	5216597 A	01-06-1993
EP 0462466	A	27-12-1991	AT	151547 T	15-04-1997
			AU	631316 B	19-11-1992
			AU	7801091 A	19-03-1992
			CA	2043198 A	21-12-1991
			DE	69125531 D	15-05-1997
			DE	69125531 T	17-07-1997
			DK	462466 T	06-10-1997
			ES	2100183 T	16-06-1997
			GR	3023253 T	30-07-1997
			IL	98203 A	18-06-1996
			KR	201193 B	15-06-1999
			ZA	9104666 A	24-06-1992
WO 9728737	A	14-08-1997	FI	960637 A	13-08-1997
			AU	1726797 A	28-08-1997
			EP	0883371 A	16-12-1998
			JP	2000503556 T	28-03-2000
			US	5840020 A	24-11-1998

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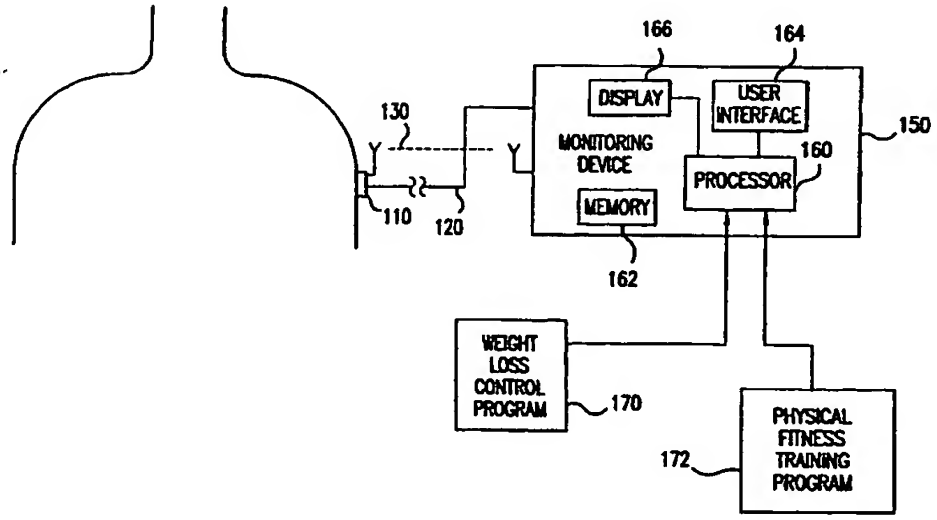
(54) Title: SYSTEM AND METHOD FOR MONITORING GLUCOSE TO ASSIST IN WEIGHT MANAGEMENT AND FITNESS TRAINING



(57) Abstract: A system and method to manage an individual's weight by setting a maximum desired glucose level for an individual; recording glucose levels at multiple times during a day for the individual so as to obtain glucose levels after at least one meal event of the individual; and comparing post meal glucose levels with the maximum desired glucose level. A system and method are provided to assist an individual in fitness training or exercise, comprising recording glucose levels of an individual while the individual is undergoing physical exercise; comparing glucose levels during physical exercise with a threshold level; and generating an indicator when the glucose level during physical exercise is below the threshold level.

WO 00/78208 A1

SYSTEM AND METHOD FOR MONITORING GLUCOSE TO ASSIST IN WEIGHT MANAGEMENT AND FITNESS TRAINING

This application claims priority to U.S. Provisional Application No. 60/139,943, filed June 18, 1999, the entirety of which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

The present invention is directed to glucose monitoring, and more particularly to the use of continuous glucose measurements for personal fitness management.

Research and development efforts are being made to provide technology that makes glucose monitoring less invasive and disruptive to an individual's daily life. Some systems involve the use of implantable sensor devices, which have drawbacks such as the need for surgery to implant the sensor and the associated risks of infection. Another type of system is much less invasive and involves collecting on a continual basis biological fluid from small openings made in the skin. Such a system is disclosed in co-pending PCT Application No. PCT/US99/16378, filed July 20, 1999, and entitled "System and Method for Continuous Analyte Monitoring." This type of system is proving to be more promising for use on a large scale basis.

The ability to automatically continuously or repeatedly monitor glucose levels of an individual over extended periods of time during an individual's normal daily routine makes it possible to monitor metabolic activity. In particular, monitoring glucose level on a continual basis provides insight into eating habits that lead to weight (gain or loss) management, and into fitness performance.

SUMMARY OF THE INVENTION

The present invention is directed to a system and method for using glucose measurements obtained from an individual on a continuous basis to manage an individual's weight gain or loss and exercise or fitness performance.

In accordance with one embodiment of the invention, a system and method are provided to manage an individual's weight by setting a maximum desired glucose level for an individual; recording glucose levels at multiple times during a day for the individual so as to obtain glucose levels after at least one meal event of the individual; and comparing post meal glucose levels with the maximum desired glucose level.

In accordance with another embodiment, a system and method are provided to assist an individual in fitness training or exercise, comprising recording glucose levels of an individual while the individual is undergoing physical exercise; comparing glucose levels during physical exercise with a desired level or threshold; and generating an indicator when the glucose level during physical exercise is below the threshold level.

The above and other objects and advantages of the present invention will become more readily apparent when reference is made to the following description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a block diagram of a system according to the present invention.

FIG. 2 is a diagram of a fluid collection and sensor device useful in connection with the present invention.

FIG. 3 is a flow chart depicting a weight management process according to an embodiment of the invention.

FIG. 4 is a flow chart depicting a fitness management process according to an embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

FIG. 1 illustrates a glucose monitoring system 100 comprising a tissue-mounted fluid collection and assay device 110 and a monitoring device 150. The fluid collection and assay device 110 is coupled to the monitoring device 150 by a wired link 120 or a wireless link 130. An example of a monitoring system suitable for

use in conjunction with the present invention is the monitoring system disclosed in the aforementioned co-pending PCT Application No. PCT/US99/16378, the entirety of which is incorporated herein by reference. Other examples of fluid collection and sensor devices are disclosed in co-pending PCT Application No. PCT/US99/16226, filed July 20, 1999, and entitled "System and Method for Fluid Management in a Continuous Fluid Collection and Sensor Device," and in PCT Application No. PCT/US00/09393, filed April 7, 2000, and entitled "Assay Device for Measuring Characteristics of a Fluid on a Continual Basis."

With reference to FIG. 2, the fluid collection and assay device 110 is positioned on the tissue proximate to one or more openings 180 made in the tissue to collect biological fluid, such as blood or interstitial fluid. The openings in the tissue may be made by any suitable technique and apparatus known in the art, such as lancet, needle, micro-needle, thermal microporation, etc. An example of a thermal microporation technique is disclosed in U.S. Patent No. 5,885,211. Vacuum may be applied to the fluid collection and assay device 110 from the monitoring device 150 via a conduit 190 to draw fluid from the tissue on a periodic or continuous basis when it is desired to make a reading. Conduit 190 may contain the wired link 120 (FIG. 1). When biological fluid is drawn into the device 110, it contacts an assay element 112 in the fluid collection and assay device 110. The assay element 112 may be any type of glucose assay element known in the art, such as an electrochemical bio-sensor, optically read sensor, etc. Readings are made from the assay element 112 by the monitoring device 150, either electrically via electrodes disposed in or on the assay element 112, or optically. Further details about a fluid collection and assay device 110 are disclosed in the aforementioned PCT applications. An advantage of the continuous analyte monitoring system and methods disclosed in these related applications is the ability to extract and analyze new samples of biological fluid from the same tissue openings over an extended period of time, such as throughout an entire day, several days or longer.

Referring back to FIG. 1, the monitoring device 150 comprises a processor 160 suitable for performing calculations on the readings taken from the assay element in the fluid collection and assay device to derive measurements, such as glucose measurements. The processor 160 may be a microprocessor, application specific integrated circuit (ASIC), digital signal processor, or any other device capable of performing computations necessary for the processes of the present invention.

In one form, the processor 160 is a microprocessor that executes one or more programs stored in a memory 162. Memory 162 is any type of a read only memory (ROM), random access memory (RAM) or a combination thereof suitable for storing a program that contains the instructions for the processes described herein, as well as storing data obtained from measurements and other information derived from that data. One program that may be made available to the processor 160 is a weight loss control program 170 and another is a physical fitness training program 172. These programs may be based on separate instructions or derived from a common set of instructions.

The monitoring device 150 optionally includes a user interface 164 to enable input of information from a user. The user interface 164 is, for example, an alphanumeric keypad, a touch-screen user interface, voice recognition interface, handwriting recognition interface, etc. Programming of parameters into the monitoring device 150 may also be achieved via the user interface 164. A display 166 is also optionally provided to display information such as glucose levels, status information, information being input into the monitoring device by a user, and other messages or information communications from the monitoring device 150 to the user.

The human body produces glucose for nourishment of cells. When production of glucose varies, excess glucose is converted into fat for storage, or the fat is metabolized to produce glucose when glucose levels are low. It is on this principle that the present invention is based. These production mechanisms and rates can be monitored using a continuous glucose monitoring system such as the one shown in FIG. 1. Monitoring glucose levels can provide insight into foods and eating habits,

which lead to weight gain and loss, as well as to energy level and consumption rates in physical exercise.

According to one aspect of the invention, glucose levels are monitored on a continual basis to aid in the selection of nutritional consumption by providing a mechanism to monitor the results of consumption. The impact of certain foods in a particular individual can be assessed by monitoring the amount and rate of glucose produced. Guidelines can be set to achieve desired and controlled weight gain or loss. Similarly, according to another aspect of the invention, by monitoring a person during exercise, the type, rate and duration of the exercise can be assessed based on the glucose consumption and production amounts and rates. Through long term monitoring of changes in these conditions, information can be created to optimize a person's fitness endurance and performance.

Turning to FIG. 3 in conjunction with FIG. 1, a process is shown for a weight management program such as that shown at reference numeral 170 in FIG. 1. In step 200, a maximum desired glucose level is set. This level may be derived by a trained professional (such as a physician) from physical characteristics including body mass index and percentage body fat, and an individual's goals for weight loss or gain. A numeric value corresponding to this maximum level is stored in the weight management program. The storage mechanism may be via an infra-red, radio frequency, or other wireless programming technique to convey information to the monitoring device 150. Alternatively, a keypad or touch-screen is provided on the housing of the monitoring device 150 that allows user or physician access to program the monitoring device 150.

Next, in step 210, the monitoring device 100 records glucose levels at programmed times during the course of a day. For example, the monitoring device 150 will obtain and record readings 288 times a day (every 5 minutes). The number of readings taken may vary so long as readings are taken before and after every anticipated meal event for that user. In step 220, a user logs meal events into the monitoring device 150. The mechanism for logging meal events may be by actuating

a button on the monitoring device 150, triggering a command via wireless, voice or audio command, or any other action via the user interface 164. Moreover, the monitoring device 150 may be responsive to a logging event to initiate several readings at various timed intervals to be sure to obtain sufficient data around the meal event. It is particularly important to obtain sufficient readings after the meal event.

In step 230, the post meal glucose levels are compared with the maximum glucose level. When and if a post meal glucose level exceeds the maximum level, in step 240 the monitoring device 150 may generate an alert indicator that is audio, visual or any combination. In addition, the processor 160 stores an indication of the fact that the maximum level was exceeded. By keeping track of when the maximum glucose level is exceeded, the user may adjust a meal plan or eating habits in step 250. For example, the user may try eating other types of foods or combinations of foods to achieve a lower intake of simple sugars at a particular meal event. The process is repeated from step 210 for a new or modified meal. Also, the maximum glucose level may be adjusted if necessary after sufficient information is learned about the individual. Moreover, the maximum glucose level can be used as a target to achieve as part of a process to achieve weight gain for a particular user.

One method of enabling the user to keep track of the various foods eaten at each meal is through user interaction with the monitoring device 150 and additional intelligence provided in the monitoring device 150. In step 220, when a user logs a meal event, or at any other time convenient to the user, the user may enter information into the monitoring device 150 via the user interface 164 that identifies each food item ingested for a meal event. In this manner, the monitoring device 150 can track which item or items may be contributing to a high glucose reading and inform the user accordingly to assist the user in modifying food selection accordingly to prevent glucose levels from going above the maximum glucose level. This may be achieved through a program and database stored in the monitoring device 150 that is capable of identifying those food items most likely to contain high levels of simple sugars. Moreover, when a user informs the monitoring device 150 of the food items for a

particular meal, the monitoring device 150 may suggest to the user lower quantities of a particular food item if that item was one eaten by the user at that meal, or perhaps suggest other food items known to have less impact on glucose levels. Communication of information from the monitoring device 150 to the user may be in the form of an alphanumeric message or synthesized voice message generated by the processor 160 and displayed on the display 166. This type of communication between the monitoring device 150 and the user may occur during step 250 or any other time when the user may inquire of the monitoring device 150 of eating plans or suggestions.

Referring to FIG. 4 in conjunction with FIG. 1, a process for managing fitness exercise or training will be described. In step 300, glucose levels are recorded to a user's fitness routine or exercise circuit. The monitoring system 100 shown in FIG. 1 is suitable to be worn by a user during nearly any type of physical activity. When a user is about to begin an exercise of fitness activity, a command is given to the monitoring device 150 to initiate the fitness management program so that glucose measurements are taken at appropriate time intervals during the fitness event. The number and frequency of the measurements may vary depending on the duration of the fitness event.

A threshold glucose level is computed in step 310 based on the measurements taken in step 300. The threshold is a goal or desired level and is physiologically dependent on the individual. For example, it may be 10 mg/dL below a fasting glucose level for an individual.

Once the threshold glucose level is computed, in step 320 the user begins his/her fitness routine or exercise circuit and glucose levels are recorded at appropriate time intervals during the fitness event. The monitoring device 100 compares the recorded glucose levels with the threshold level. The monitoring device 100 generates an indication when the glucose level during the fitness event is below the threshold level. The monitoring device 100 may generate (audio, visual or a combination thereof) alerts during the fitness event when the user's glucose level

drops below the threshold level. Alternatively, or in addition to the alerts, the monitoring device may generate historical data summary reports that can be viewed on a personal computer, on a display of the monitoring device itself, or sent to a printer for hard copy. The historical data summary report will indicate when (in time and/or during certain exercises) during the fitness event the glucose level dropped below the threshold level. With this information, the user may modify the exercise routine in step 350 to prevent such a glucose drop. For example, the user may modify the intensity, duration and/or type of exercise in order to maintain sufficient glucose levels, thereby preventing overexertion and/or reduction of muscle mass. Moreover, extended glucose monitoring can help a user determine which foods support extended level glucose periods during exercise. The user may enter information into the monitoring device that describes the type of foods ingested at a meal event. Interaction between the user and the monitoring device similar to that described above in conjunction with the weight management program may also be used in the fitness management program.

The above description is intended by way of example only.

Claims:

1. A method for assisting an individual in weight management, comprising steps of:

setting a maximum desired glucose level for an individual;

recording glucose levels at multiple times during a day for the individual so as to obtain glucose levels after at least one meal event of the individual; and

comparing post meal glucose levels with the maximum desired glucose level.

2. The method of claim 1, and further comprising the step of generating an indicator when it is determined that a post meal glucose level exceeds the maximum glucose level.

3. The method of claim 2, and further comprising the step of generating a indicator or signal that advises the individual to alter eating habits so as to prevent glucose levels from going above the maximum glucose level.

4. The method of claim 1, and further comprising the step of receiving input from the individual indicating the occurrence of a meal event.

5. The method of claim 1, and further comprising informing the individual of a food item for a meal event that may be responsible for higher glucose levels.

6. A system for monitoring glucose levels of an individual to assist in weight management, comprising:

a sensor that detects glucose in biological fluid obtained from an individual;

a processor coupled to the sensor, the processor being operative to:

store data representing a maximum glucose level for an individual;

store data representing glucose levels determined from the sensor at multiple times during a day so as to obtain glucose levels after at least one meal event of the individual; and

compare post meal glucose levels with the maximum glucose level.

7. The system of claim 6, wherein the processor generates an indicator when it is determined that a post meal glucose level exceeds the maximum glucose level.

8. The system of claim 6, wherein the processor generates a signal that advises the individual to alter eating habits so as to prevent glucose levels from going above the maximum glucose level.

9. The system of claim 6, wherein the processor generates information to inform the individual of a food item for a meal event that may be responsible for higher glucose levels.

10. A method for assisting an individual in fitness training or exercise, comprising steps of:

recording glucose levels of an individual while the individual is undergoing physical exercise;

comparing glucose levels during physical exercise with a threshold level; and

generating an indicator when the glucose level during physical exercise is below the threshold level.

11. The method of claim 10, and further comprising the step of modifying physical exercise intensity, duration and or selection such that glucose levels substantially throughout the period of physical exercise are at or above the threshold level.

12. The method of claim 10, and further comprising the step of modifying eating habits to achieve glucose levels that are at or above the threshold level substantially throughout the period of physical exercise.

13. The method of claim 10, and further comprising the step of determining the threshold level based upon glucose levels recorded during physical exercise and a physiologically dependent goal.

14. A system for monitoring glucose levels of an individual to assist in fitness training or exercise, comprising:

a sensor that detects glucose in biological fluid obtained from an individual;

a processor coupled to the sensor, the processor being operative to:

store data representing glucose levels determined from the sensor during periods of physical exercise of the individual;

compare glucose levels during the physical exercise with a threshold level; and

generate an indicator when the glucose level during physical exercise is below the threshold level.

15. The system of claim 14, wherein the processor generates a signal advising the individual to modify physical exercise intensity, duration and/ or selection such that glucose levels substantially throughout the period of physical exercise are at or above the threshold level.

16. The system of claim 14, wherein the processor generates a signal advising the individual to modify eating habits to achieve glucose levels that are at or above the threshold level substantially throughout the period of physical exercise.

17. The system of claim 14, wherein the processor determines a threshold glucose level based on glucose levels recorded during physical exercise and a desired physiologically dependent goal of the individual.

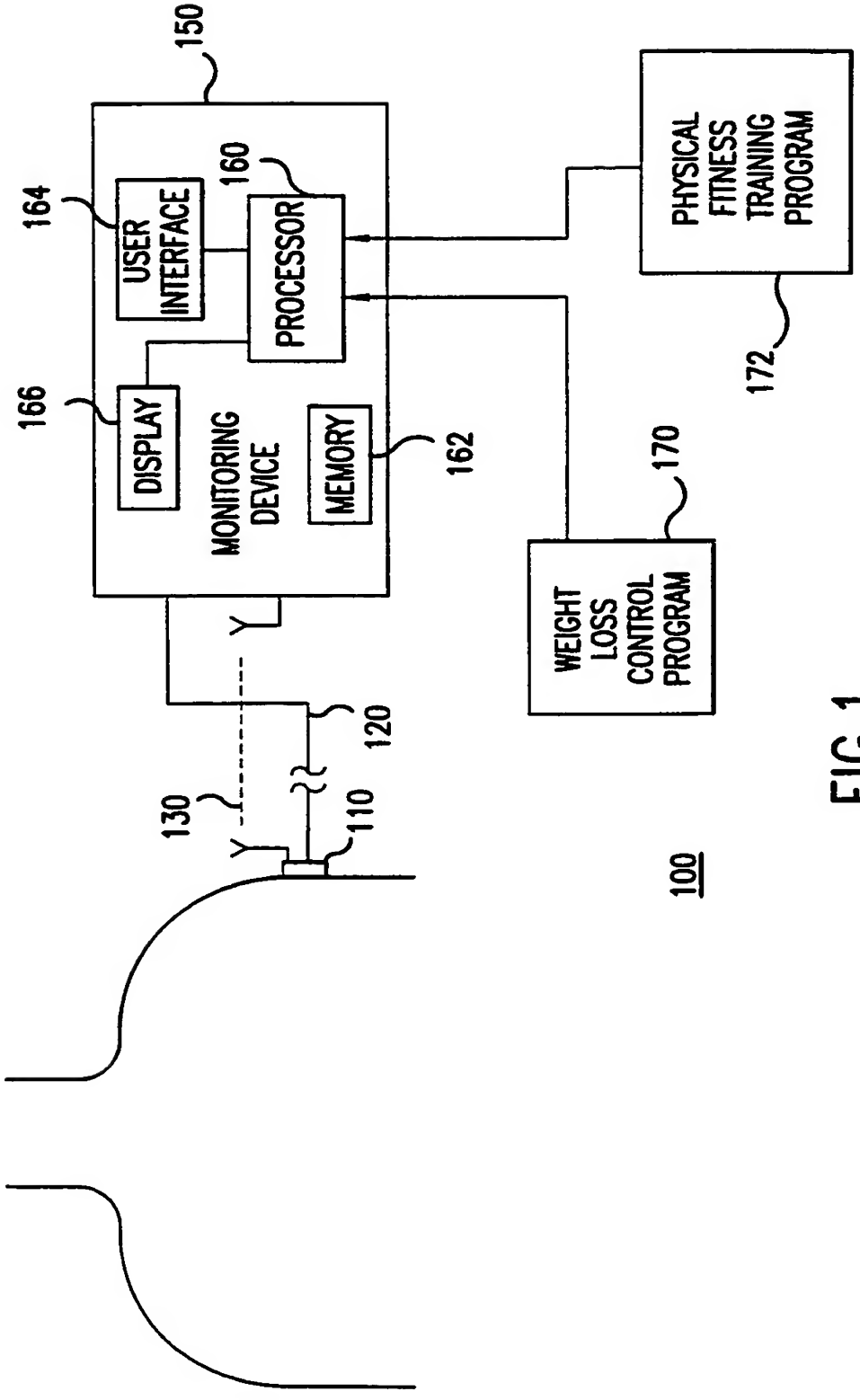

150
164
USER INTERFACE
160
PROCESSOR
PHYSICAL FITNESS TRAINING PROGRAM
172
166
DISPLAY
MONITORING DEVICE
MEMORY
162
170
WEIGHT LOSS CONTROL PROGRAM
120
130
110
100

FIG.1

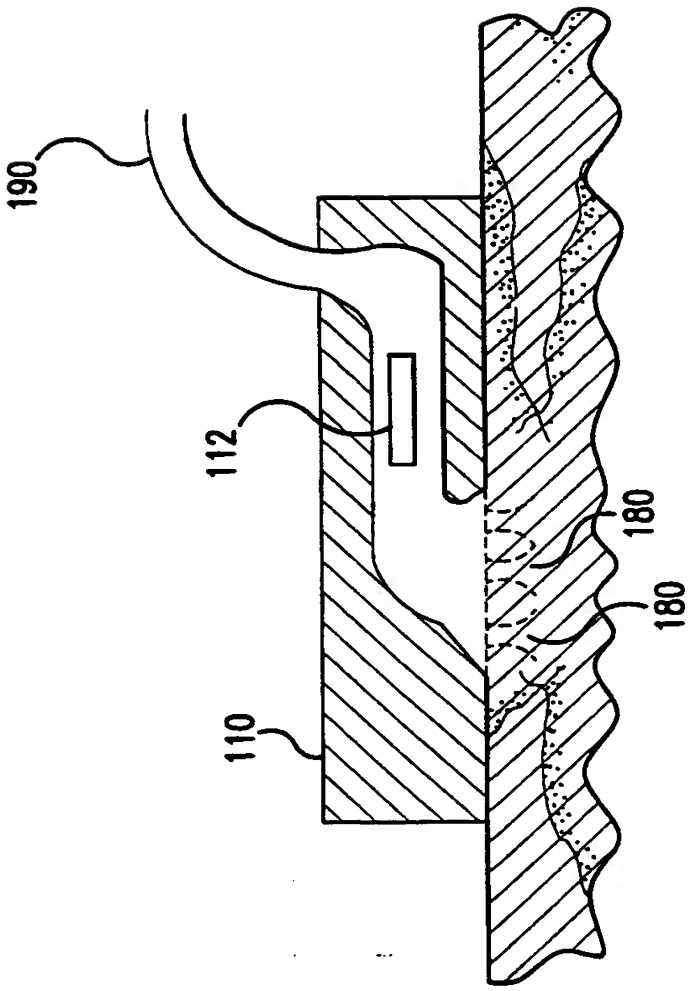


FIG.2

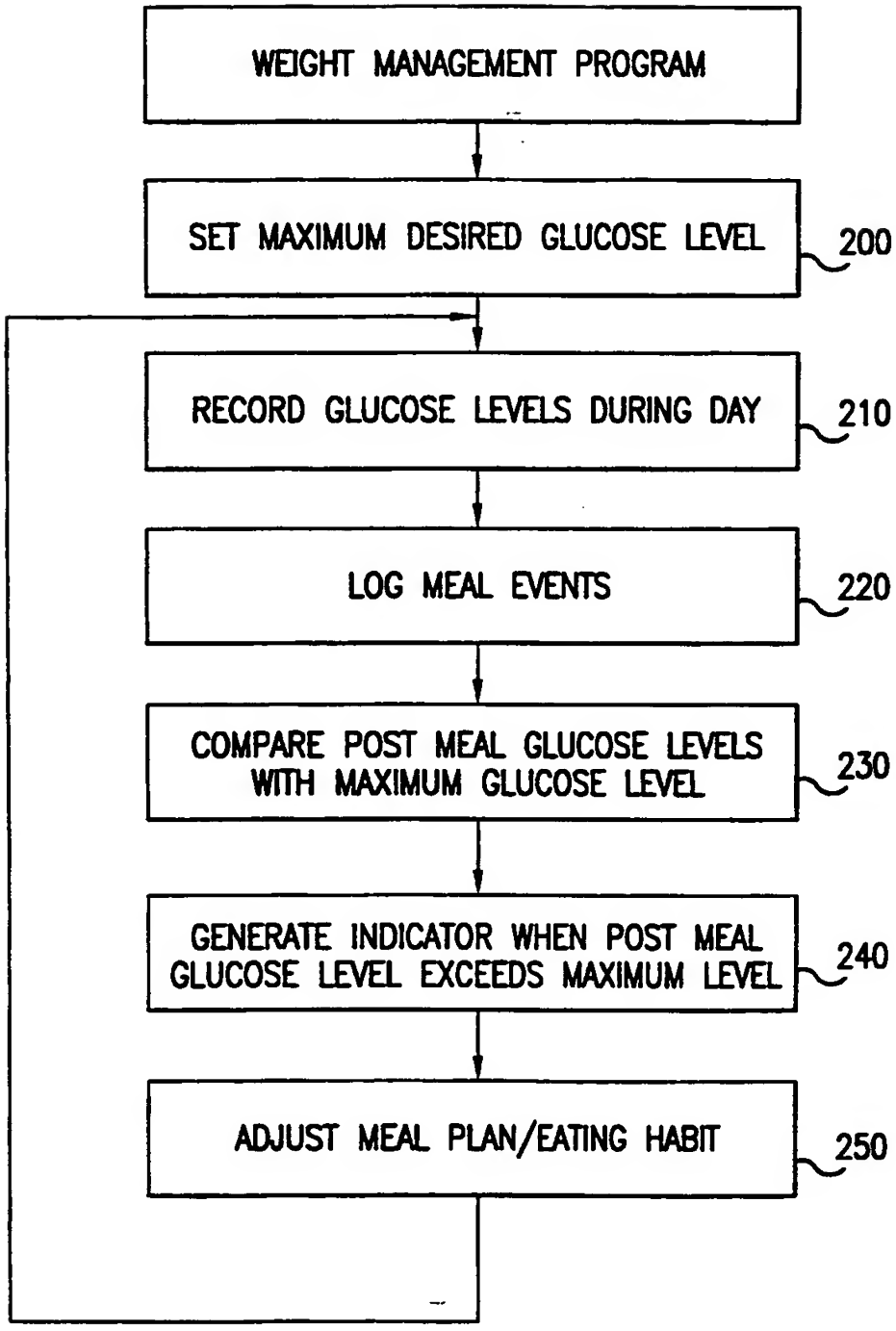

WEIGHT MANAGEMENT PROGRAM
SET MAXIMUM DESIRED GLUCOSE LEVEL
200
RECORD GLUCOSE LEVELS DURING DAY
210
LOG MEAL EVENTS
220
COMPARE POST MEAL GLUCOSE LEVELS WITH MAXIMUM GLUCOSE LEVEL
230
GENERATE INDICATOR WHEN POST MEAL GLUCOSE LEVEL EXCEEDS MAXIMUM LEVEL
240
ADJUST MEAL PLAN/EATING HABIT
250

FIG.3

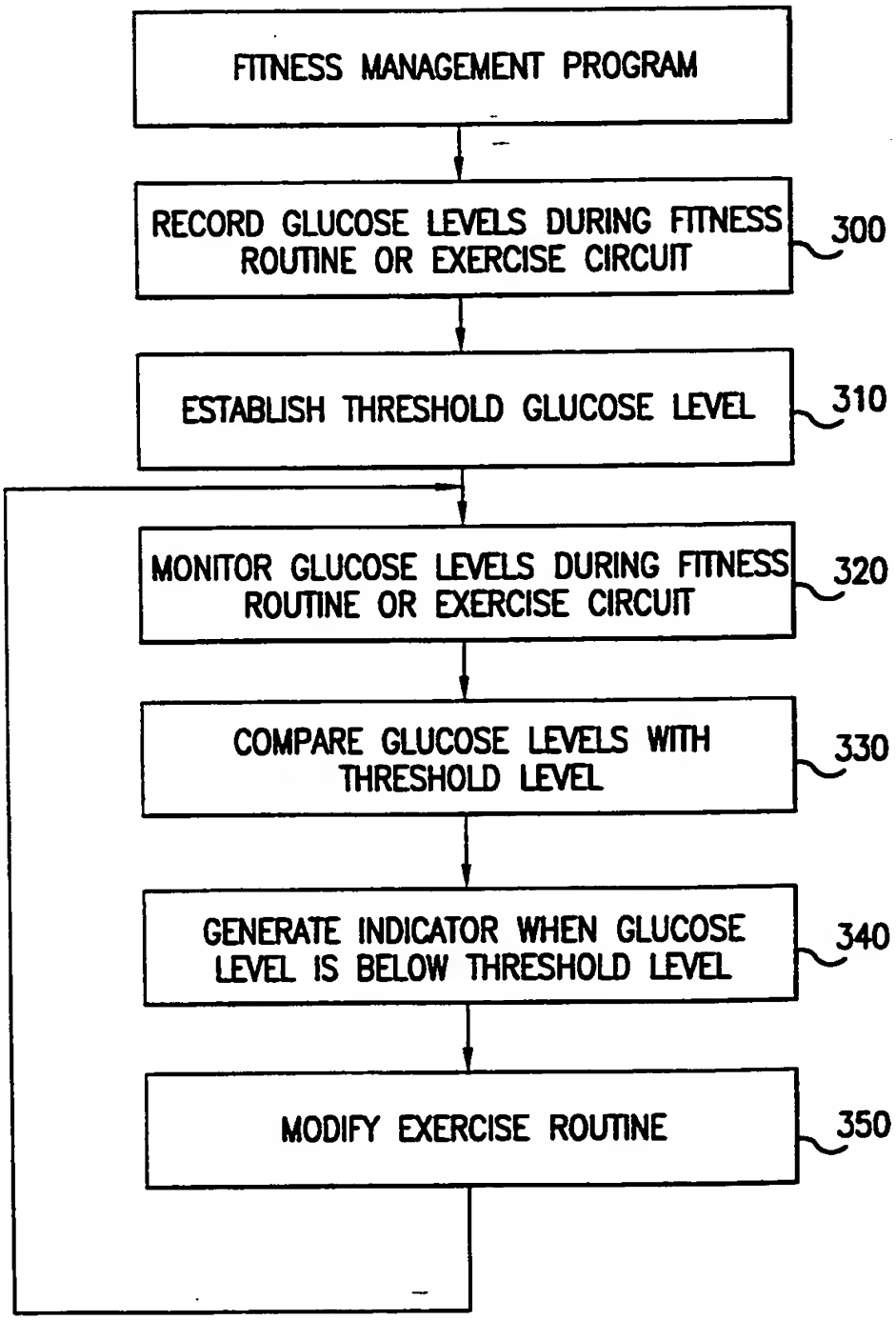

FITNESS MANAGEMENT PROGRAM
RECORD GLUCOSE LEVELS DURING FITNESS ROUTINE OR EXERCISE CIRCUIT
300
ESTABLISH THRESHOLD GLUCOSE LEVEL
310
MONITOR GLUCOSE LEVELS DURING FITNESS ROUTINE OR EXERCISE CIRCUIT
320
COMPARE GLUCOSE LEVELS WITH THRESHOLD LEVEL
330
GENERATE INDICATOR WHEN GLUCOSE LEVEL IS BELOW THRESHOLD LEVEL
340
MODIFY EXERCISE ROUTINE
350

FIG.4